

AWARD NUMBER: W81XWH-13-2-0080

TITLE: Study of Tranexamic Acid During Air Medical
Prehospital Transport Trial (STAAMP trial)

PRINCIPAL INVESTIGATOR: Jason L. Sperry, M.D., MPH

CONTRACTING ORGANIZATION: University of Pittsburgh, Pittsburgh, PA 15213

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13. SUPPLEMENTARY NOTES					
14. ABSTRACT The enrollment for this study began at the University of Pittsburgh on 11-JUN-2015. External sites are in the process of submitting their initial IRB application and the community consultation plan is either in the development stage or recently initiated. Pittsburgh Coordinating Center is awaiting IRB approval regarding changes to the protocol language.					
15. SUBJECT TERMS Prehospital; Tranexamic acid					
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INTRODUCTION:

- The primary hypothesis is that the prehospital infusion of tranexamic acid in patients at risk for bleeding will reduce the incidence of 30 day mortality. The secondary hypotheses include that prehospital tranexamic acid will reduce the incidence of hyperfibrinolysis, acute lung injury, multiple organ failure, nosocomial infection, mortality, early seizures, pulmonary embolism and early resuscitation needs, reduce or prevent the early coagulopathy as demonstrated by improving presenting INR and rapid thromboelastography parameters, reduce the early inflammatory response, plasmin levels, leukocyte, platelet and complement activation, and determine the optimal dosing of tranexamic acid post-injury.

1. **KEYWORDS:** Provide a brief list of keywords (limit to 20 words).

- Prehospital
- Tranexamic acid

2. **OVERALL PROJECT SUMMARY:** Summarize the progress during appropriate reporting period (single annual or comprehensive final). This section of the report shall be in direct alignment with respect to each task outlined in the approved SOW in a summary of Current Objectives, and a summary of Results, Progress and Accomplishments with Discussion. Key methodology used during the reporting period, including a description of any changes to originally proposed methods, shall be summarized. Data supporting research conclusions, in the form of figures and/or tables, shall be embedded in the text, appended, or referenced to appended manuscripts. Actual or anticipated problems or delays and actions or plans to resolve them shall be included. Additionally, any changes in approach and reasons for these changes shall be reported. **Any change that is substantially different from the original approved SOW (e.g., new or modified tasks, objectives, experiments, etc.) requires review by the Grants Officer's Representative and final approval by USAMRAA Grants Officer through an award modification prior to initiating any changes.**

- Pittsburgh site completed Community Consultation for Pittsburgh and surrounding areas.
- University of Pittsburgh Coordinating Center received approval for Protocol Modification Version 1.4 by IRB on 20-Nov-2014
- University of Pittsburgh site received approval for Protocol Modification Version 1.4 by IRB on 20-Nov-2014
- An investigator teleconference was held in Oct-2014 with each participating site; investigator and coordinator from each site were present
- An investigator teleconference was held in FEB-2015 with each participating site; investigator and coordinator from each site were present
- Secretary of Defense approval for Pittsburgh Coordinating Center was received on 13-MAY-2015
- Secretary of Defense approval for Pittsburgh performing site was received on 13-MAY-2015
- UTHSCSA site received final approval to implement Community Consultation on 27-MAY-2015
- Coordinating Center IRB annual renewal approved 24-JUN-2015
- Pittsburgh site received IRB approval for additional Sub-investigators on 25-JUN-2015
- STAAMP Investigator Meeting was held at AAST SEP-2015, representatives from all sites were present.

3. **KEY RESEARCH ACCOMPLISHMENTS:** Bulleted list of key research accomplishments emanating from this research. Project milestones, such as simply completing

proposed experiments, are not acceptable as key research accomplishments. Key research accomplishments are those that have contributed to the major goals and objectives and that have potential impact on the research field.

- Pittsburgh site began enrollment on 11-JUN-2015.
- University of Rochester will serve as an alternate site
- Added the University of Arizona as a participating site

4. CONCLUSION: Summarize the importance and/or implications with respect to medical and /or military significance of the completed research including distinctive contributions, innovations, or changes in practice or behavior that has come about as a result of the project. A brief description of future plans to accomplish the goals and objectives shall also be included.

- External sites are in the process of submitting their initial IRB application and the community consultation plan is either in the development stage or recently initiated
- We are in the process of collecting all outstanding documentation for the external sites to submit to HRPO. Upon receipt of the HRPO approval for the sites, the Coordinating Center will conduct Site Initiation Visits and activate sites to begin enrollment. The enrollment at all sites is expected to start in Spring 2016.
- Data entry web based platform is in development (this will be a secure web based Electronic Data Capture).
- Pittsburgh Coordinating Center is awaiting IRB approval regarding changes to the protocol language and plan to submit the modification to the DOD.

5. PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS:

- a. List all manuscripts submitted for publication during the period covered by this report resulting from this project. Include those in the categories of lay press, peer-reviewed scientific journals, invited articles, and abstracts. Each entry shall include the author(s), article title, journal name, book title, editors(s), publisher, volume number, page number(s), date, DOI, PMID, and/or ISBN.

(1) Lay Press: ***Nothing to report***

(2) Peer-Reviewed Scientific Journals:

Design of the Study of Tranexamic Acid during Air Medical Prehospital Transport (STAAMP) Trial: Addressing the Knowledge Gaps.

Brown JB, Neal MD, Guyette FX, Peitzman AB, Billiar TR, Zuckerbraun BS, Sperry JL. Prehosp Emerg Care. 2015 January-March;19(1):79-86. Epub 2014 Jul 30.

PMID: 25076119

(3) Invited Articles: ***Nothing to report***

(4) Abstracts: ***Nothing to report***

- b. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.
- ***Summary of the process and enrollment to the TACTIC investigators at their bi-annual meeting***

6. INVENTIONS, PATENTS AND LICENSES: List all inventions made and patents and licenses applied for and/or issued. Each entry shall include the inventor(s), invention title, patent

application number, filing date, patent number if issued, patent issued date, national, or international.

- ***Nothing to report***

- 7. REPORTABLE OUTCOMES:** Provide a list of reportable outcomes that have resulted from this research. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. This list may include development of prototypes, computer programs and/or software (such as databases and animal models, etc.) or similar products that may be commercialized.

- ***Nothing to report***

- 8. OTHER ACHIEVEMENTS:** This list may include degrees obtained that are supported by this award, development of cell lines, tissue or serum repositories, funding applied for based on work supported by this award, and employment or research opportunities applied for and/or received based on experience/training supported by this award.

- ***Nothing to report***

For each section, 4 through 9, if there is no reportable outcome, state “Nothing to report.”

- 9. REFERENCES:** List all references pertinent to the report using a standard journal format (i.e., format used in *Science*, *Military Medicine*, etc.).

- 10. APPENDICES:** Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

NOTE:

TRAINING OR FELLOWSHIP AWARDS: - ***Nothing to report***